

PATENT
Attorney Dkt. No.: 92030/03-071

REMARKS

Claims 14-16, 18, 21, 53-58, 60 and 62-72 are pending in the application. Claims 14-16, 21, 53-57, 62-65, and 68-72 were allowed in the Office Action of September 22, 2006. Claims 21, 56, 58, 60, 62-63, and 70 were allowed in the Office Action of January 30, 2007. Claims 14, 54, 55, 57, 65, and 67-69 are amended herein. Claims 14-16, 18, 53, 57, 64, 66, and 71 are rejected. Claims 54, 55, 65, 67-69, and 72 are objected to. Claims 1-13, 17, 19, 20, 22-52, 59 and 61 are canceled. Claims 14-16, 18, 21, 53-58, 60 and 62-72 remain for consideration.

Claim Rejections – 35 USC §102; Ray et al.

The Examiner rejects claims 14-16, 18, 53, 57 and 71 as being anticipated by Ray et al. (U.S. Patent No. 5,026,373). The Examiner states:

Ray et al discloses an interbody spine fusion (50) comprising a body (53) defining an outside surface, a carrier (57), a carrier receiving area (56 & 52), implanting the bone implantable device adjacent a target bone structure (see Fig. 9), applying biologically active substance onto the carrier after said step of implanting for subsequent delivery to said target bone structure (see col. 8, lines 36-41; col. 10, lines 6-12).

Regarding claim 15, see col. 10, lines 6-7.

Regarding claim 16, see col. 10, lines 10-11.

With regard to independent claim 14, claim 14 is amended to clarify that the carrier is comprised of a material that is different from a material comprising the bone implantable device. Applicant provides examples of suitable materials for forming the device, including titanium, alloys, carbon fiber, bone or ceramic (para. [0060]). Applicant further provides examples of suitable carriers including material capable of absorbing or otherwise holding a bone growth

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inducing agent (para. [0059]), bovine collagen material (para. [0084]) and sponge material (para. [0082]).

The Examiner is interpreting Ray et al.'s end cap 57 as a carrier. End cap 57 is a part of interbody spine fusion cage 50. Ray et al.'s example materials for interbody spine fusion cage 50 include stainless steel (Fig. 1) (col. 10, line 48); and titanium (col. 10, line 66). Ray et al. do not teach an end cap or carrier that is comprised of a material that is different from a material comprising said bone implantable device as is set forth in claim 14. Allowance of amended claim 14 is requested.

With regard to claims 15 and 16, each depend from amended claim 14, which is submitted to be patentable. Dependent claims 15 and 16 are submitted to be patentable for at least this reason.

Claim 15 is additionally submitted to be patentable for at least the reason that Ray's step of packing the cage with bone chips referenced by the Examiner at col. 10, lines 6-11 does not anticipate Applicant's claim language, "applying said carrier into said carrier receiving area" for the reason that Ray et al. do not teach using the bone chips as a "carrier," but instead teach that the bone chips themselves are a "bone-inducing substance" (col. 10, lines 20, 21).

Claim 16 is additionally submitted to be patentable for at least the reason that Ray's step of packing the cage with bone chips referred by the Examiner at col. 10, line 6-11 does not teach, "injecting a biologically active substance through an injection port" Instead, Ray teaches that, "the cage is packed with bone chips ... and the second end cap is applied...." In particular, Ray teaches no "injecting" or any "injection port" as is required by claim 16.

Independent claim 53 is submitted to be patentable for at least the same reasons set out with regard to claim 15, above, i.e., Ray et al. teaches no "carrier."

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Independent claim 57 is amended to clarify that the carrier material is "doped with" a biologically active substance. As argued with regard to claims 15 and 53, above, Ray does not teach a "carrier material," nor does Ray teach doping any material with a biologically active substance.

Claim 71 is submitted to be patentable over Ray et al. While Ray et al. do teach the use of a bone inducing substance (col. 10, line 20), i.e., "bone chips or *other bone inducing substance*" (col. 10, lines 10, 11), Ray et al. could not have contemplated a "fluidal bone growth agent" as required by claim 71 since Ray et al. teaches no carrier with which to absorb or otherwise hold or contain a fluidal agent. Reconsideration and allowance of claim 71 is requested.

Claim Rejections - 35 USC §102; White et al.

The Examiner rejects claims 64 and 66 under 35 U.S.C. 102(e) as being anticipated by White et al. (US 6,409,764). The Examiner states:

White et al discloses a bone implantable device (78) (see Fig. 9) comprising a body (12), a carrier receiving area (10), an pre-loaded collagen carrier (67) comprising a biologically active substance (69 or 71). Additionally, see col. 10, lines 37-40.

Regarding claims 64 and 66, Applicant was unable to locate any teachings in White et al that carrier matrix 67, referred to by the Examiner as a "pre-loaded collagen carrier," is "pre-loaded," as is set forth by claims 64 and 66.

Applicant located several teachings regarding the implantation procedure, including the following at (col. 15, lines 45-48):

At or soon after plant of the TP device, the space established within the body of the mammal by implantation of the TP device contains a carrier substance...

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Admittedly, the above quote is ambiguous. However, insofar as Applicant is aware, all other references to the procedure, including references in provided "examples," indicate that the collagen carrier is not "pre loaded" as required by claim 64. For example, the paragraph of col. 15, lines 50-60 indicates that a scaffold is presented after implantation. Col. 18, lines 17-21 states that "The absorbable collagen sponge that carries the rhBMP-2 is placed within the established space." Example 3, col. 29 and Example 4, col. 31 indicate that ACS strips are laid down first, then the TP device.

Applicant, therefore, asserts that White et al. does not teach a pre-loaded carrier as is required by claims 64 and 66. Applicant requests allowance of claims 64 and 66.

Claim Rejections – 35 USC §112

The Examiner rejects claim 57 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states:

Claim 57 recites the limitation "said port" in line 10. There is insufficient antecedent basis for this limitation in the claim.

Claim 57 is amended to remedy the antecedent basis rejection.

Allowable Subject Matter

Claims 14-16, 21, 53-57, 62-65, and 68-72 were allowed in the Office Action of September 22, 2006. Claims 21, 56, 58, 60, 62-63, and 70 were allowed in the Office Action of January 30, 2007.

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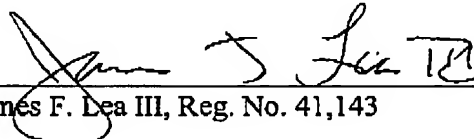
Claims 54, 55, 65, 67-69, and 72 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Considering the foregoing, it is sincerely believed that this case is in condition for allowance, which is respectfully requested.

This paper is intended to constitute a complete response to the outstanding Office Action. Please contact the undersigned if it appears that a portion of this response is missing or if there remain any additional matters to resolve. If the Examiner feels that processing of the application can be expedited in any respect by a personal conference, please consider this an invitation to contact the undersigned by phone.

Respectfully Submitted,

4-17-07
Date


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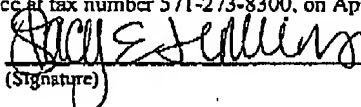
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CERTIFICATE OF MAILING UNDER 37 CFR 1.8

I hereby certify that this correspondence and any document referred to as being attached thereto is being transmitted via facsimile to Examiner Alvin J. Stewart in Art Unit 3738 in the U.S. Patent Office at fax number 571-273-8300, on April 17, 2007.

Stacy E. Jenkins
(Type name of person mailing paper)


(Signature)

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